

NOV 1 2002

K023198

# 510(K) SUMMARY

Submitter of 510(k): SB LUCIUS, INC.  
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Contact person: Dae-Kyu Chang  
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Date of Summary: Sept. 16, 2002

Trade name: CERANUM 90  
Common: Dental casting alloy  
Classification name: Gold based alloys and precious metal alloys for clinical use  
Product code: EJT  
Classification: Class II

Legally marketed device: Jel Bios 90  
510(k) number: K001196

## SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

Test methods applied: as in ANSI/ADA 5 and ISO 9693

### Comparison of composition:

#### COMPOSITION (WEIGHT , %)

Device Name	Au	Pt	Pd	Ag	CU	Sn	FE	Zn
Jel Bios 90	90.00	7.40	-	1.0	-	-	<1.0	<1.0
Ceranium 90	90.00	4.00	11.95	0.05	0.2	0.40	0.15	1.00

### Comparison of physical and mechanical properties:

Alloy	Melting Point Range (°F)	Hardness (Vickers)	Yield Strength (MPa)	Elongation (%)	CTE (x10 <sup>-6</sup> /°C)	Density (g/cm3)
Jel Bios 90	1,920-2,085	160.0	386	8.0	14.6	18.8
Ceranium 90	2,012-2,102	145.7	255	16.76	15.03	19.25

**Discussion:**

Since the composition of the legally marketed alloy and the new device is very similar, it may be assumed that the biological compatibility of the alloys is also very similar.

**Conclusion:**

The main elements and their concentration are almost identical. CERANUM 90 is a High Noble, Micro-fine, Yellow, Gold based alloy to be used for inlays, onlays, single crowns, bridge, implant superstructures and substrate for medium expansion with lower fusing porcelains and indirect restorative composites. CERANUM 90 is a high gold ceramic alloy, which heightens the porcelain esthetics of the restoration and provides strength, durability and color of gold. Despite minor differences in the materials, we believe that CERANUM 90 is a substantially equivalent to J.F.JELENKO's Jel Bios 90. These changes do not affect safety or effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. Dae-Kyu Chang  
SB Lucius, Incorporated  
9778 Katella Avenue, Suite 205  
Anaheim, California 92804

Re: K023198

Trade/Device Name: Ceranum 90  
Regulation Number: 21 CFR 872.3060  
Regulation Name: Gold-Based Alloys and Precious Metal Alloys for Clinical Use  
Regulatory Class: II  
Product Code: EJT  
Dated: September 16, 2002  
Received: September 25, 2002

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

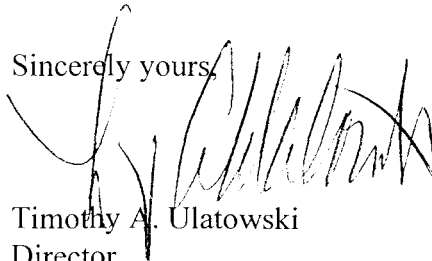
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You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## SB LUCIUS, INC.

9778 Katella Ave.

Ste.205, Anaheim, CA 92804

Phone: (714) 530-2814,

Fax : (714) 530-3448,

### INDICATIONS FOR USE

510(K) Number : K023198

Device Name(s) : CERANUM 90

This is a yellow ceramic alloy for single units, implants prosthetics, single & 3/4 crowns, and short span bridges.

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(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER  
PAGE IF NEEDED)

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CONCURRENCE OF CHRD, OFFICE OF DEVICE EVALUATION(OED)

Sharon R. Brown  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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